Appendix A

Anchoring of Model Parameters

INTRODUCTION

The *Escherichia coli* O157:H7 risk assessment model is essentially a process risk model that describes the occurrence and levels of this pathogen across the farm-to-table continuum. All such models include parameters that are intended to be deterministic. However, knowledge about these parameters is often uncertain.

The resolution for each model parameter depends on the quantity and quality of the data available about that parameter. Different data types and sources are often used to estimate the various parameters in the model. As described in this report, each *E. coli* O157:H7 risk assessment model parameter was independently calibrated from available evidence and scientific knowledge. During the model development stage, however, parameter calibration did not include consideration of the model outputs.

Because the parameters are independently calibrated from data of varying quality and quantity, it is expected that there are combinations of these parameters that, when used in the model, predict outcomes that are entirely inconsistent with what has been observed. The knowledge used to describe the uncertainty about parameters before running the model is less than that available after running the model. After running the model, it becomes clear that some parameter values are not feasible given the available evidence about the model's output. These infeasible values, or combinations of values, should be used to improve the resolution of the input parameters and, consequently, the model's predictions. The evidence used to define infeasible values is often referred to as validation data.

One output of the *E. coli* O157:H7 risk assessment model for which validation data exist is the prevalence of *E. coli* O157:H7-contaminated grinder loads. Since 1994, the Food Safety and Inspection Service (FSIS) has treated various raw chopped or ground beef products that contain *E. coli* O157:H7 as adulterated under the Federal Meat Inspection Act unless they are further processed in a manner that destroys this pathogen. In October 1994, FSIS initiated a

microbiological testing program for *E. coli* O157:H7 in raw ground beef in meat plants and retail stores. The testing program operated under FSIS Notice 50-94, issued December 23, 1994, until the agency issued FSIS Directive 10,010.1 on February 1, 1998. Based on the low concentrations of *E. coli* O157:H7 recovered from samples of frozen ground beef patties identified in a 1993 outbreak, FSIS increased the sample size from 25 grams to 325 grams in FY 1998 to enhance efficiency and the likelihood of detecting pathogens in raw ground beef sold to consumers. In September 1999, microbiologic testing was changed to include immunomagnetic separation methods.

Approximately 1,900 plants under FSIS inspection produce ground beef. Each month, FSIS randomly selects an appropriate number of inspected plants for sample collection. The sampling plan is based on information from Centers for Disease Control and Prevention (CDC) sentinel sites, historic data on foodborne illness outbreaks, and other information. If a plant initiates its own routine sampling program, has a certification from suppliers that the product was tested, or uses in-plant validated pathogen reduction interventions on beef carcasses, FSIS will not collect samples.

The ground beef sampling data can only calibrate those parts of the model that describe events leading up to the creation of grinder loads. Therefore, most of the parameters described for the preparation module are not informed by these data. Nevertheless, because the inputs to the preparation module are calibrated, its outputs are influenced by these data. The outputs include distributions that describe the frequency of exposure to different doses of *E. coli* O157:H7 in ground beef servings.

METHODS

Uncertainty about each model input is described in the three exposure assessment modules. Various probability density functions are used to capture this input uncertainty. Generically, these distributions are summarized by $p\left(\hat{\theta} \mid y_{\hat{\theta}}\right)$, where $\hat{\theta}$ represents a vector of all i inputs and $y_{\hat{\theta}}$ is the evidence available to estimate each $\hat{\theta}_i$ (Green et al. 2000).

Before the production and slaughter modules are run, uncertainty about the prevalence of contaminated grinder loads is based on 2000 FSIS ground beef sampling data (Table A-1). These data are used because they represent an entire year, incorporate the same sampling and testing methods, and are based on very sensitive culture methods.

Ground beef sampling results depict apparent prevalence. As noted previously, apparent prevalence is less than true prevalence because sample size and culture methods do not ensure that every sample from a contaminated source contains organisms or that the laboratory methods will detect those organisms present in the sample. The FSIS sampling data—when assumed to be beta distributed (Vose 1996)—predict the mean annual apparent prevalence as 0.52% with 5th and 95th percentile values of 0.36% and 0.71%, respectively. The seasonal results demonstrate that there were significantly more positive samples in the high prevalence season (June to September) than in the low prevalence season (October to May).

This output uncertainty can be generically summarized as $p(\phi|y_\phi)$, where ϕ is the prevalence of positive ground beef samples given y_ϕ, the appropriate seasonal sampling evidence.

TABLE A-1 FSIS Ground Beef Sampling Results for 2000. These 325-gram samples were collected in federally inspected ground beef processing plants.

Season	Positive	Tested	5th Percentile	Mean	95th Percentile
Low prevalence (October–May)	10	3,139	0.20%	0.35%	0.54%
High prevalence (June–September)	13	1,447	0.59%	0.97%	1.42%
Annual	23	4,586	0.36%	0.52%	0.71%

A method for calibrating process models using input and output uncertainty has been reported (Green et al. 2000). Before running the model, the joint probability of the inputs and outputs is represented by $p(\phi,\hat{\theta} \mid y_{\phi}, y_{\hat{\theta}}) = p(\phi \mid y_{\phi}) \times p(\hat{\theta} \mid y_{\hat{\theta}})$. In other words, the probability of different combinations of input values and output values is predicted independently from each input and output distribution. Before running the model, therefore, the joint probability of a more likely input value and a more likely output value is greater than the joint probability of less likely values from the input or output distribution or both.

When simulated in sequence, the production and slaughter modules generate distributions for levels of *E. coli* O157:H7 in combo bins. The preparation module simulates mixing combo bins to generate grinder loads with varying levels of *E. coli* O157:H7. For calibration, the model output of interest is the prevalence of positive samples from grinder loads.

Sampling from grinder loads is simulated to mimic the FSIS methods by assuming 325-gram samples and the current FSIS culture methods. The probability that a sample contains x organisms is predicted by *Poisson* (325 × GLC), where GLC is the grinder load concentration described in the preparation module. The probability of a positive test equals $1-(1-s)^{x}$, where s is the probability that laboratory methods detect a single organism in a sample.

Evidence concerning the likelihood of detecting *E. coli* O157:H7 in ground beef comes from an experimental study (Okrend et al. 1990). In that study, 25-gram samples of ground beef were each inoculated with an average of 18 *E. coli* O157:H7, and eight of nine samples (89%) were positive. The probability of a positive sample was assumed to equal $1 - (1 - s)^{18}$. In this case, s equaled 0.11. The 2000 FSIS sampling results reflect the use of immunomagnetic separation methods in addition to culture. On the basis of discussions with FSIS microbiologists, it is assumed that s is four times greater than methods described in Okrend et al. (1990).

The model selects random combinations of inputs to predict an output. Therefore, the model (M) transforms inputs into outputs (i.e., $M(\hat{\theta}) \rightarrow \phi$). Before running the model, all combinations of inputs and outputs were possible. After running the model, certain combinations are not supported. For example, combinations of inputs that predict high prevalence and high levels of *E. coli* O157:H7 in combo bins cannot result in a model prediction of low apparent prevalence in ground beef. The joint probability of these combinations must be zero. The joint probabilities of combinations that are supported by the model are proportional to their premodel probabilities. Therefore, the most feasible combinations are those that predict apparent prevalence levels consistent with the sampling evidence.

To calibrate the model, the following steps are taken:

1. A random draw from each uncertain parameter is taken.
2. The production, slaughter, and preparation modules are simulated for 10,000 iterations each.

3. For each grinder load concentration (GLC_i) simulated, the probability of a positive test is calculated as $P_{GLC_i}(+) = \sum_{x=0}^{\infty}[1-(1-s)^{x_i}]\times f(x)$, where $s = 0.44$ and

$$f(x) = \frac{(325\times GLC_i)^x \times e^{-325\times GLC_i}}{x!}.$$

4. The prevalence of positive ground beef samples is calculated as $P(+) = \sum_{GLC_{min}}^{GLC_{max}} P_{GLC_i}(+)\times f(GLC_i)$, where $f(GLC_i)$ is the frequency of each GLC (in half-log increments) predicted by the model.
5. If the calculated $P(+)$ for the simulation is less than the 95th percentile of the FSIS ground beef sampling evidence for the appropriate season (Table A-1), then the simulation is considered to represent a feasible combination of inputs. Otherwise, that combination is considered infeasible.
6. If the calculated $P(+)$ for the simulation is less than the 5th percentile of the FSIS ground beef sampling evidence for the appropriate season (Table A-1), then each GLC_i is incrementally increased by 0.5 logs until $P(+)$ is as close to the mean of the ground beef sampling evidence as possible. This adjustment serves to estimate the effect of the fabrication step of the slaughter module.
7. Steps 1 through 6 are repeated until a sufficient set of feasible combinations is collected.

The feasible set of production and slaughter inputs is perpetuated through the preparation module to predict exposure distributions.

RESULTS

Figure A-1 shows the similarity between the distribution for prevalence of positive ground beef samples based on FSIS sampling evidence for the low prevalence season and that estimated after running the model. The central tendency of the distribution based solely on the sampling evidence is slightly less compared with the model distribution's central tendency. Nevertheless, the difference in means from the two distributions is negligible (0.35% vs. 0.36%).

Figure A-2 shows a similar relationship for the high prevalence season. The FSIS sampling evidence and the distribution predicted by the model overlap considerably. The means of the two distributions are also very similar (0.96% for the FSIS sampling evidence and 0.94% for the model distribution).

Differences observed between the two distributions are primarily a result of the fabrication algorithm wherein half-log increments are added to grinder concentrations. Half-log increments were chosen primarily for convenience but can result in substantial shifts in the modeled values. More precise overlap between the sampling evidence and model might be achieved by using more refined increments. Furthermore, the model output is based on a set of 100 feasible simulations. More simulations would also refine the model's distribution.

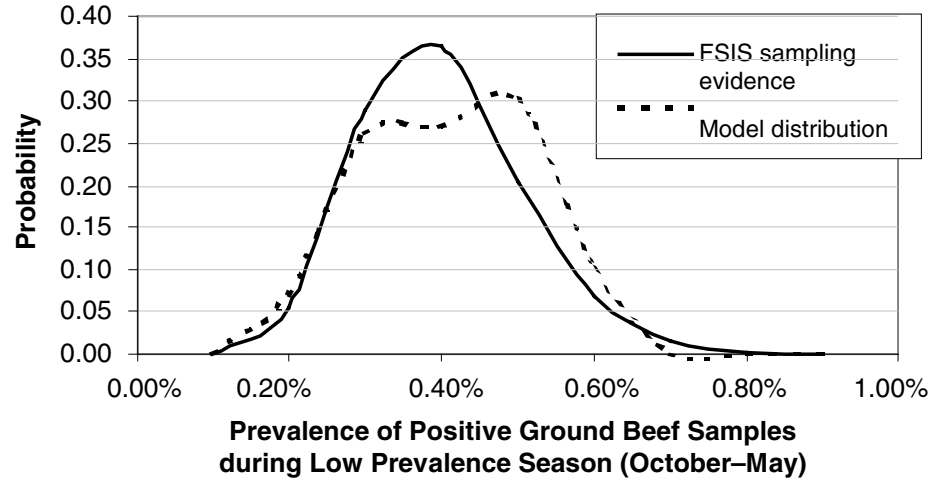

FIGURE A-1 Comparison of probability distributions for apparent prevalence of *E. coli* O157:H7-contaminated grinder loads using the FSIS sampling evidence (Table A-1) and the risk assessment model. These distributions are based on sampling evidence and model simulations for the low prevalence season.

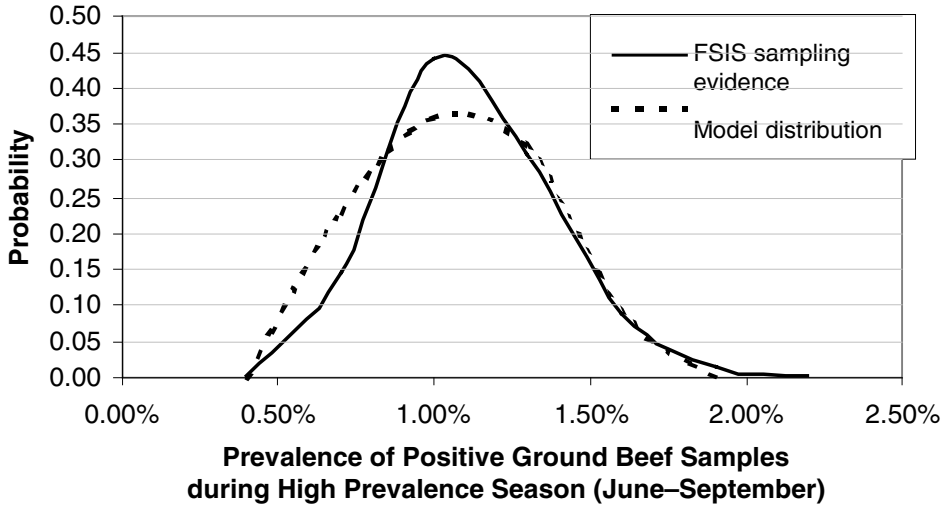

FIGURE A-2 Comparison of probability distributions for apparent prevalence of *E. coli* O157:H7-contaminated grinder loads using the FSIS sampling evidence (Table A-1) and the risk assessment model. These distributions are based on sampling evidence and model simulations for the high prevalence season.

REFERENCES

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